K030007

ATTACHMENT 6

MAR 31 2003

510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert
Director, Regulatory Affairs

2. **Name of the Device**

Trade Name:	ITI® DENTAL IMPLANT SYSTEM
Common Name:	Endosseous dental implants
Classification Name:	Endosseous dental implants 21 CFR 872.3640

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI Dental Implant System (K984104, K003552)
Various Branemark System Implants (K022562)

4. **Description of the Device**

ITI solid screw implants have an external spiral screw thread and an anchorage surface that is grit blasted then acid etched (SLA surface) or titanium plasma-sprayed (TPS surface). The implants are composed of Grade 4 titanium, cold worked. The neck of the implant, intended to remain above the crest of the bone on implantation, is a smooth machined surface to allow for the attachment of epithelial tissue. ITI implants are available in a range of endosseous diameters (3.3 to 4.8 mm) and lengths.

5. **Indications for Use**

Like the predicate Branemark implants, the ITI Dental System implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients 4 or more implants must be used.

6. **Basis for Substantial Equivalence**

The subject ITI® dental implants are identical in intended use to currently marketed ITI® dental implants, and the indications for use covered in this 510(k) are the same as that of the predicate Branemark system dental implants.

The subject ITI® implants are identical in all respects to previously cleared ITI implants. There has been no change in material, surface treatment, design, or operating principle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2003

Ms. Linda Jalbert
Director, Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K030007
Trade/Device Name: ITI® Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implants
Regulatory Class: III
Product Code: DZE
Dated: December 31, 2002
Received: January 1, 2003

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030007

510(k) Number (if known): K030007

Device Name: ITI Dental Implant System

Indications For Use:

The ITI dental implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients 4 or more implants must be used.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Mosley for MSP
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030007